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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/047,693 | 01/09/2002 | Istvan Bakondi-Kovacs | 2664/47002 | 5182 |

26646 7590 12/17/2004

KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

MARX, IRENE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/047,693

Applicant(s)

BAKONDI-KOVACS ET AL.

Examiner

Irene Marx

Art Unit

1651

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on 30 November 2004. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ They raise the issue of new matter (see NOTE below);

(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-27.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☐ Other: _____.

Irene Marx
Primary Examiner
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Note:

The proposed amendment raises new issues that would require further consideration and/or search with respect to the amendments to replace “preparing” with fermenting and the addition of “in the fermentation broth to improve the yield of the 6’-O-carbamoyl tobramycin” in claim 1. New issues are also raised by the broadening of “glucose” to “carbon source” in claims 4-6, and the broadening of “ammonia nitrogen” to “nitrogen source” in claims 14-15 including new issues under 35 U.S.C § 112.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The arguments are directed to claims that are not entered and are not persuasive of error in the rejection made.

Applicant appears to argue that there is no motivation to combine the fermentation process of Vanek *et al.* with the fermentation processes of Ott *et al.* and Tomita *et al.* to produce tobramycin because Vanek *et al.* does not produce tobramycin. However, Vanek *et al.* is similarly directed to fermentation processes and is relied upon to demonstrate that the use of chemostats in fermentation processes is old and well known in the art. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, regulation at a constant level is a claimed process step but it has not been shown to be the sole parameter required to affect growth and/or productivity of any tobramycin producing microorganism in the actual yield and/or recovery of tobramycin. The invention as claimed provides no clear correlation between the regulation of any carbon source and any nitrogen source in any amount and recovery of tobramycin. Therefore, the teachings of Ott *et al.* and Tomita *et al.* and Vanek *et al.* are properly combined.

Moreover, there is no indication of record that yield of 6’-O-carbamoyl tobramycin may be improved merely by using constant levels of any carbon and nitrogen source. The invention as claimed requires the preparation of a fermentation broth containing a microorganism, and regulating a constant level of carbon and nitrogen. The amount in the “constant level” is not claim designated, except for individual components. It is well recognized that antibiotic

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production is influenced by the nitrogen, carbon and phosphate sources used in the medium. In addition careful examination of the written disclosure indicates that the metabolic controlled approach fermentation was conducted with *S. tenebrarius* wherein all of glucose, glutamate and ammonia nitrogen are controlled at specific levels in the medium. Thus, applicant has failed to demonstrate that "constant level" is all that is required to achieve the touted results.

Therefore the rejection is deemed proper and it is adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651